PIEZOSURGERY®

Piezosurgery s.r.l.
Registered Office:
Molo Ponte Morosini 41/7 - 16126 Genoa, Italy
Headquarter:
Via Portobello, 12 - 16039 Sestri Levante, Italy
Tel:+39 0185 450863, Fax:+39 0185 42799
E-mail: piezosurgery@piezosurgery.com

K091227

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DEC 2 9 2009

510(k) Summary

1.	**Submitter's information**	Mectron S.p.A. Via Loreto 15/A 16042 Carasco (GE), Italy Tel. +39 0185 35361 Fax +39 0185 351374 E-mail: mectron@mectron.com
2.	**510(k) Contact person**	Enrico Perfler Executive Manager, Regulatory & Quality Assurance Meditrial s.r.l. Via Aldo Moro, 20 - 25124 Brescia, Italy Tel: +39 0185 474 847 Fax: +39 0185 394 904 Cell: +39 347 074 7145 Email: e.perfler@meditrial.eu
3.	**Summary's date**	3 April 2009
4.	**Device name and classification**	
	a. **Trade/device name**	OSSTEMPiezo
	b. **Classification name**	Bone cutting instrument and accessories (per 21 CFR section 872.4120) Ultrasonic scaler (per 21 CFR section 872.4850)
	c. **Classification panel**	Dental
	d. **Regulatory class**	Class II
	e. **Product code**	DZI, ELC

5. Device description

The OSSTEMPiezo uses piezoelectric ultrasonic technology to generate mechanical microvibrations for bone cutting and ultrasonic scaling, with minimal trauma to soft tissue. The device is supplied with sharp, smoothing and blunt insert tips for use in oral surgery, including implantology, periodontal surgery, endodontic surgery and surgical orthodontics.

6. Intendend use/Indications for use

The OSSTEMPiezo is intended for use in the following dental applications:

- Bone cutting for use in oral surgery
- Removing supra and subgingival calculus deposits and stains from teeth
- Periodontal pocket lavage with simultaneous ultrasonic tip movement
- Scaling and root planing
- Retrograde preparation of root canals

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7. Predicate device

Piezosurgery® device (K052518).

8. Performance evaluations

The device uses piezoelectric ultrasonic technology to generate mechanical microvibrations of insert tips for cutting mineralized structures with minimal trauma to soft tissue and for ultrasonic scaling. The insert tip microvibration results in a safe and effective cut, preserving the osteotomized surfaces, surgical tactile control, reduction of risk of adjacent tissue damage, reduction of tissue heating, and improved post-operative healing. The evaluations demonstrated precisely delineated incisions and the need for limited pressure on the handpiece to achieve the desired cutting action, which improves surgical control and reduces the possibility of trauma to soft tissue.

9. Conclusion

We believe the information provided in this premarket notification support a finding of substantial equivalence between the OSSTEMPiezo and the predicate device Piezosurgery currently marketed.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

FEB 22 2010

Piezosurgery S.R.L.
C/O Mr. Ing. Enrico Perfler
Executive Manager, Regulatory and Quality Assurance
Meditrial S.R.L.
Via Aldo Moro
20 – 25124 Brescia
ITALY

Re: K091227
Trade/Device Name: Piezosurgery 3, OSSTEMPiezo
Regulation Number: 21CFR 872.4120
Regulation Name: Bone Cutting Instrument and Accessories
Regulatory Class: II
Product Code: DZI, ELC
Dated: December 17, 2009
Received: December 22, 2009

Dear Mr. Perfler:

This letter corrects our substantially equivalent letter of December 29, 2009.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at 240-276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K091227

Indications for Use

510(k) Number (if known): _____

Device Name: Piezosurgery 3

Indications for Use: The Piezosurgery 3 is intended for use in the following dental applications:

- Bone cutting for use in oral surgery
- Removing supra and subgingival calculus deposits and stains from teeth
- Periodontal pocket lavage with simultaneous ultrasonic tip movement
- Scaling and root planing
- Retrograde preparation of root canals

RS Betz DDS for Dr. K.P. Murthy (Acting)
(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K091227

Prescription Use ___X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)